

REMARKS/ARGUMENTS

Applicants have studied the Office Action dated December 30, 2008, and have made amendments to the claims. It is submitted that the application, as amended, is in condition for allowance. Claims 1 to 5 and 7 to 35 remain in the application. Claims 1 to 5, 7 to 12 and 26 to 35 are subject to examination and claims 13 to 25 have been withdrawn from examination. Claims 1, 27, 29, 30, and 31 to 34 have been amended. Claim 6 has been cancelled. Reconsideration and allowance of the pending claims in view of the above amendments and the following remarks is respectfully requested.

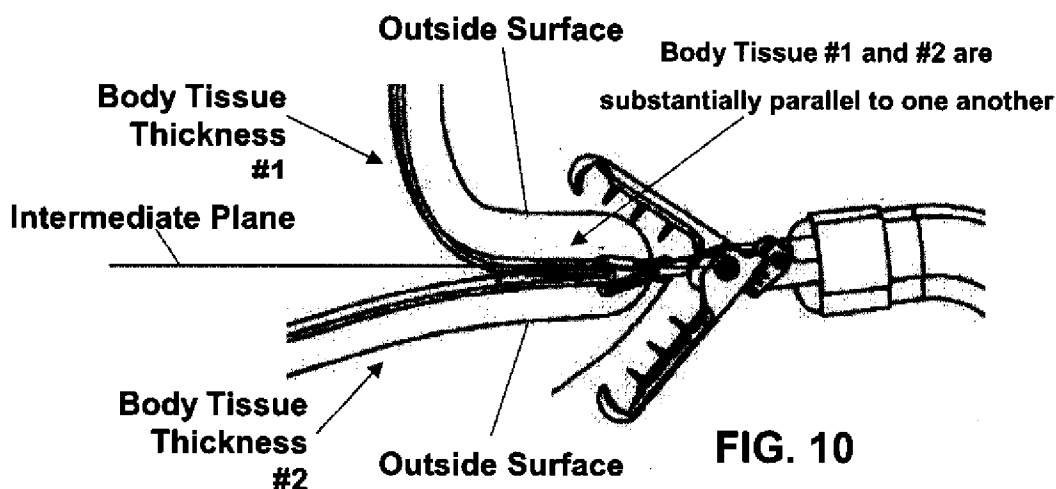
In the Office Action, the Examiner:

- (1) acknowledged the entering of applicants' amendment filed on September 15, 2008;
- (2) withdrew the allowability of claims 2 to 5, 27, 28, 31, 32, 34, and 35;
- (3-4) rejected claim 33 under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement;
- (5-6) rejected claim 30 under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicants regard as the invention;
- (7-8) rejected claims 1, 2, 4, 5, 11, 12, 26 to 35 under 35 U.S.C. § 102(b) as being anticipated by Yoon (U.S. 5,620,452);
- (9-12) rejected claim 3 under 35 U.S.C. § 103(a) as being unpatentable over Yoon (U.S. 5,620,452) in view of Nakao et al (U.S. 5,156,609; hereinafter "Nakao"); and
- (13) rejected claims 7 to 10 under 35 U.S.C. § 103(a) as being unpatentable over Yoon (U.S. 5,620,452) in view of Harrison et al (U.S. 5,403,326; hereinafter "Harrison").

(3-4) Rejection under 35 U.S.C. §112, first paragraph

The Examiner rejected claim 33 under 35 U.S.C. § 112, first paragraph as failing to comply with the written description requirement. Applicants believe the specification does contain the subject matter of claim 33 as to reasonably convey to one skilled in the relevant art that the inventors had possession of the claimed invention at the time the application was filed.

Support for the limitation of “disposing two thicknesses of body tissue substantially parallel to one another to define an intermediate plane and two opposing outside surfaces substantially parallel to said intermediate plane” is found, for example, in Figures 10 to 14 of the originally filed application. Figure 10 is reproduced below for the Examiners convenience.



As shown in Figure 10, the two thicknesses of body tissue (#1 and #2) are substantially parallel to each other after the jaws of the clip applicator close onto, for example, the invaginated fundus. See application at page 17, last paragraph. When the tissue is folded as shown, it defines an intermediate plane, which is illustrated in the figure above. This intermediate plane is a geometric line created by and based upon the two thicknesses of body tissue being folded onto each other. Moreover, the two opposing outside surfaces of the body tissue are substantially parallel to the intermediate plane.

Applicants believe that Figure 10 adequately discloses the subject matter described in claim 33.

In view of the remarks above, therefore, Applicants believe that the rejection of claim 33 under 35 U.S.C. § 112, first paragraph, has been overcome. Applicants respectfully request withdrawal of this rejection.

(5-6) Rejection under 35 U.S.C. §112, second paragraph

The Examiner rejected claim 30 under 35 U.S.C. § 112, second paragraph as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention.

Because the application of the clamping force to the body tissue is part of the advancing step, claim 29 only has two steps: an advancing step and a bending step. Applicants have amended claim 30 to more clearly and affirmatively recite that a single instrument performs the advancing and bending steps.

In view of the amendment to claim 30 and the remarks above, Applicants believe that the rejection of claim 30 under 35 U.S.C. § 112, second paragraph, has been overcome. Applicants respectfully request withdrawal of this rejection.

(7-8) Rejection under 35 U.S.C. §102(b)

As noted above, the Examiner rejected claims 1, 2, 4, 5, 11, 12, and 26 to 35 under 35 U.S.C. § 102(b) as being anticipated by Yoon (U.S. 5,620,452). The claims have been amended to more clearly define the invention and overcome the cited prior art.

Before discussing the prior art in detail, it is believed that a brief review of the invention as claimed, would be helpful. Independent claim 1 recites, *in relevant part*:

subsequently advancing a clip over said folded body tissue, said clip having two substantially parallel arms each having a respective piercing portion and a bridge coupling the two arms, such that said body tissue is located between said two arms and such that said clip applies force to said folded body tissue, **each of the piercing portions being non-perpendicular to the respective associated one of the arms before being bent.** (Emphasis added.)

Independent claim 27 recites, *in relevant part*:

advancing the clip over the folded portion of body tissue in the longitudinal direction to place the folded portion between the two arms and to apply force to the folded portion with the clip, **each of the piercing portions being parallel to the respective associated one of the arms before being bent.** (Emphasis added.)

Independent claim 29 recites, *in relevant part*:

advancing a clip over body tissue folded on itself to form a first portion of a fold and a second portion of the fold such that the first and second portions are located between the two arms and such that the clip applies a clamping force to the body tissue, **each of the piercing portions being substantially parallel to the respective associated one of the arms before being bent.** (Emphasis added.)

Independent claim 31 recites, *in relevant part*:

advancing a clip over body tissue folded on itself to form first and second portions of a fold disposed between the two arms and to apply a force to the folded body tissue, the folded tissue defining a longitudinal direction of the folded body tissue, the **piercing portions** of the two arms **being initially oriented along the longitudinal direction** and **substantially parallel to the respective associated one of the arms before being bent.** (Emphasis added.)

Independent claim 32 recites, *in relevant part*:

advancing a clip over body tissue folded on itself to form first and second portions of a fold disposed between the two arms and to apply a force to the folded body tissue, the folded tissue defining a longitudinal direction of the folded body tissue, the **piercing portions** of the two arms **being initially oriented along the longitudinal direction** and **substantially parallel to the respective associated one of the arms before being bent.** (Emphasis added.)

Independent claim 33 recites, *in relevant part*:

advancing a clip over said outside surfaces of said body tissue, said clip having two substantially parallel arms each having a respective piercing portion and a bridge coupling the two arms, such that said body tissue is located between said two arms and such that said clip applies force to

said body tissue, **each of the piercing portions being substantially parallel to the respective associated one of the arms before being bent.** (Emphasis added.)

Independent claim 34 recites, *inter alia*:

providing a clip having:
two arms each having a piercing portion; and
a bridge coupling the two arms;

releasably coupling at least a part of one piercing portion to a respective one of the arms;

folding body tissue to form a folded portion extending along a longitudinal direction;

advancing the clip over the folded portion of body tissue in the longitudinal direction to place the folded portion between the two arms and to apply force to the folded portion with the clip, **each of the piercing portions being substantially parallel to the respective associated one of the arms before being bent;** and

bending the piercing portion of at least one of the two arms through more than one half a thickness of the folded portion at an angle to the longitudinal direction. (Emphasis added).

The present invention concerns a medical method connecting folded body tissue together by advancing a surgical clip over the body tissue and bending the piercing portion of the surgical clip but not bending the arms of the clip during this process. The body tissue is folded upon itself and the surgical clip is advanced **over** the body tissue so the body tissue is located between the two arms of the surgical clip. **Then, only the retainer portion of the surgical clip is plastically deformed to affix the clip to the fundus** (see, e.g., FIG. 13 below).

In an effort to better define the present invention, Applicants have amended the claims to more clearly show that the piercing portions of the surgical clip are not perpendicular to their respective arms prior to bending – they are **substantially parallel** thereto. The claims, as amended, provide that one property of the surgical clip is that either (claim 1) “each of the piercing portions being non-perpendicular to the respective associated one of the arms before being bent” or (claims 27, 29, and 31 to 34) “each of the piercing

portions being substantially parallel to the respective associated one of the arms before being bent." In other words, the piercing portions of the arms are positioned parallel to their respective arms before being bent plastically to affix the body tissue.

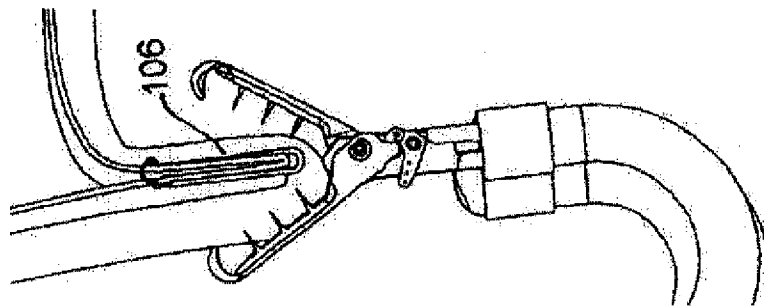


FIG. 13

The Examiner, on page 3 of the above-identified Office action, refers to FIGS. 12 and 14 of Yoon in an attempt to show anticipation of claims 1, 27, 29, and 31 to 34 of the instant application. Yoon discloses a surgical clip, shown in Figures 14 and 15 (placed below for convenience), where "[f]our staples 40, 42, 44, and 46, each having a cross member 48 and a pair of tissue penetrating legs 50 extending **perpendicularly** from opposed ends of the cross member . . . and the tissue penetrating legs 50 **extending through openings in the lower arm 18 toward the apertures 36 in the upper arm 16.**" Yoon, col. 3, lines 21-28 (emphasis added).

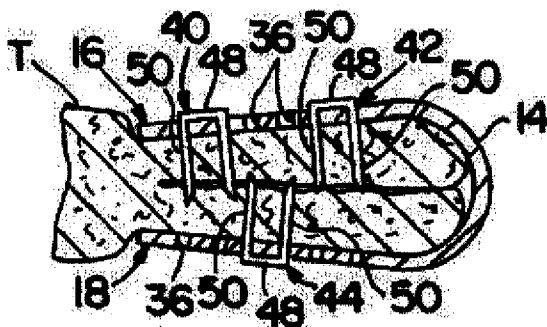


FIG. 14

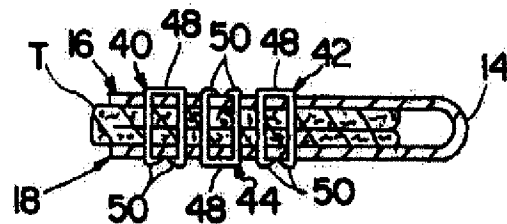


FIG. 15

The Examiner describes the staples of Yoon (40, 42, 44, and 46) as being a piercing portion of the Yoon surgical clip. Even if this single embodiment of Yoon were said to resemble a clip having two substantially parallel arms (which is not admitted to by Applicants), the clip in Yoon does not have piercing portions that remain **substantially**

parallel to their respective arms prior to deformation of the piercing portions. As described in the quoted language and as shown in FIGS. 14 and 15 displayed above, the tissue penetrating staples in Yoon are positioned *perpendicular to* the arms 16, 18 of the surgical clip. A leg that extends through openings of a lower arm 18 and toward the openings of 36 the opposing upper arm 16 cannot be described as being substantially parallel to the aforementioned arms or compared to such a configuration. Tissue penetrating legs that extend orthogonal to the longitudinal direction of two arms cannot be said to run parallel to those same arms -- the positions are mutually exclusive.

If the Examiner's conclusion is accepted (that the staples of Yoon (40, 42, 44, and 46) are the piercing portion of the Yoon surgical clip), then it is not the whole staple that is the piercing portion. Only the tissue penetrating legs 50 of the staples 40, 42, 44 can be categorized as the "piercing portion" of the clip because only these legs 50 pierce the tissue T. Yoon states that "[w]hen the arms 16 and 18 are separated by a distance somewhat less than the length of the tissue penetrating legs 50, the legs 50 pass through apertures 36 in the opposed arm and are bent around the other side as illustrated in FIG. 15" Yoon at col. 5, lines 39-42. This bending action is the only deformation of the staple, i.e., the legs 50 are the tissue piercing portions of the Yoon clip. Since this piercing portion is *always positioned perpendicular to* arms 16 and 18 of Yoon prior to bending or plastic deformation, it cannot be "substantially parallel (or non-perpendicular) to the respective associated one of the arms before being bent" as set forth in the independent claims of the instant application. Any "piercing portion" arguably found in Yoon, therefore, is described and displayed as being perpendicular to the arms of the clip before they are bent.

The Examiner's anticipation rejection also includes an argument that the Yoon clip has "two substantially parallel arms 16, 18 (Fig. 12)." This, however, is not the feature of the independent claims. Instead, claims 1, 27, 29, and 31 to 33 provide (in substantially this text): "two arms remaining substantially parallel *throughout the time said piercing portion of said at least one arm is bent.*" (Emphasis added.)

Applicants respectfully submit that the Examiner's own statements demonstrate the deficiency of this part of the anticipation rejection. More specifically, the eighth item on page 3 of the December 30, 2008 Office action provides the following: Yoon discloses "**bending the arms toward each other** (along with the piercing portions) such that the piercing portions pierce completely through the folded body tissue (Fig. 14)." (Emphasis added). However, if the Yoon clip must be manipulated to meet this recitation of the claims of the instant application, then, by definition, Yoon cannot also have arms that remain "substantially parallel throughout the time said piercing portion of said at least one arm is bent," as claims 1, 27, 29, and 31 to 33 of the instant application recite. The arms of the instant invention remain static throughout the piercing process.

A proper 35 U.S.C. § 102(b) rejection requires that a single reference teach (i.e., identically describe) each and every element of the rejected claims as being anticipated by Yoon.¹ Because the elements in independent claims 1, 27, 29, and 31 to 34 of the instant application are not taught or disclosed by Yoon, the apparatus of Yoon cannot anticipate the claims of the instant invention. The dependent claims are believed to be patentable as well because they all are ultimately dependent on either claim 1, 27, 29, 31, 32, 33, or 34. Accordingly, the instant invention distinguishes over Yoon. Applicants respectfully submit that the Examiner's rejection under 35 U.S.C. § 102(b) has been overcome.

(9-12) Rejection under 35 U.S.C. §103(a)

The Examiner rejected claim 3 under 35 U.S.C. § 103(a) as being unpatentable over Yoon (U.S. 5,620,452) in view of Nakao et al (U.S. 5,156,609). Dependent claim 3 has not been amended.

Applicants hereby incorporate the arguments made above in the section entitled "(7-8)

¹ See MPEP §2131; "A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987) (emphasis added.) . . . "The identical invention must be shown in as complete detail as is contained in the ... claim." *Richardson v. Suzuki Motor Co.*, 868 F.2d 1226, 1236, 9 USPQ2d 1913, 1920 (Fed. Cir. 1989).

Rejection under 35 U.S.C. §102(b)." As Applicants have shown the deficiencies in the Yoon as a prior art reference, Yoon in view of Nakao cannot support an obviousness rejection since Nakao does not make up for the deficiencies of Yoon. As such, it could not be obvious to one skilled in the art at the time of the invention to combine Yoon in view of Nakao, especially because Yoon does not have a surgical clip wherein each of the piercing portions are substantially parallel to the respective associated one of the arms before being bent.

Nakao discloses an endoscopic stapling device in which an unopened staple is moved toward body tissue. Nakao at col. 8, lines 66-68; col. 9, lines 1-5. When the inner tube of the Nakao device is retracted, the staple arms move while the staple goes from an open to a closed position to affix the body tissue. *Id.* at col. 9, lines 6-13; see *also* FIGS. 4H and 4I. The language "[t]he distal motion of inner tubular member 28 relative to rod member 30 and staple 32 **bends legs** 32a and 32b . . . causing staple 32 to assume a closed, tissue-clamping configuration," *id.* at col. 9, lines 9-13, makes it evident that Nakao discloses an open staple in which arms are bent to cause the staple to close on body tissue. Claim 3 refers to bending of the piercing portion of the surgical clip. The *arms* of the instant invention are not bent; they remain in a static position. Only the piercing portion of the clip is bent. Since Nakao does not disclose arms that remain substantially parallel during application of the surgical clip Nakao does not make up for the deficiency in Yoon. Therefore, Yoon in view of Nakao cannot properly serve as an obviousness rejection over any claim of the instant application, let alone claim 3.

It is accordingly believed to be clear that Yoon, whether taken alone or in combination with Nakao, neither shows nor suggests the features of claim 3. Claim 3, therefore, is believed to be patentable over the art.

(13) Rejection under 35 U.S.C. §103(a)

The Examiner rejected claims 7 to 10 under 35 U.S.C. § 103(a) as being unpatentable over Yoon (U.S. 5,620,452) in view of Harrison et al (U.S. 5,403,326). Claims 7 to 10 have not been amended.

Applicants hereby incorporate the arguments made above in the section entitled "(7-8) Rejection under 35 U.S.C. §102(b)." As dependent claims 7 to 10 ultimately depend on independent claim 1, and because Applicants have shown that Yoon does not disclose a surgical clip wherein each of the piercing portions being non-perpendicular to the respective associated one of the arms before being bent, as required by amended claim 1, Harrison cannot rectify this deficiency.

Harrison, itself, discloses a device with "moveable jaws 66 (FIG. 8A)" at col. 6, lines 61-64. Simply put, Harrison teaches away from the instant invention because its "jaws" pivot about a central point. It could not have been obvious to one of skill in the art to combine Yoon with Harrison because having arms remain in a static position during application as required in the claims is diametrically opposed to a configuration where jaws are intended and required to pivot, i.e., *they must move*.

It is accordingly believed to be clear that Yoon, whether taken alone or in combination with Harrison, neither shows nor suggests the features of claims 7 to 10. Claims 7 to 10, therefore, are believed to be patentable over the art.

CONCLUSION

The remaining cited references have been reviewed and are not believed to affect the patentability of the claims as amended.

In this Response, Applicants have amended certain claims. In light of the Office Action, Applicants believe these amendments serve a useful clarification purpose, and are desirable for clarification purposes, independent of patentability. Accordingly, Applicants respectfully submit that the claim amendments do not limit the range of any permissible equivalents.

Applicants acknowledge the continuing duty of candor and good faith to disclosure of information known to be material to the examination of this application. In accordance with 37 CFR §1.56, all such information is dutifully made of record. The foreseeable equivalents of any territory surrendered by amendment are limited to the territory taught

by the information of record. No other territory afforded by the doctrine of equivalents is knowingly surrendered and everything else is unforeseeable at the time of this amendment by the Applicants and their attorneys.

Applicants respectfully submit that all of the grounds for rejection stated in the Examiner's Office Action have been overcome, and that all claims in the application are allowable. No new matter has been added. It is believed that the application is now in condition for allowance, which allowance is respectfully requested.

If an extension of time for this paper is required, petition for extension is herewith made.

It is believed that no fee is due with this Amendment. However, if any fees are due with respect to Sections 1.16 or 1.17, please charge to the deposit account of the undersigned firm, Acct. No. 503,836.

PLEASE CALL the undersigned if that would expedite the prosecution of this application.

Respectfully submitted,

Date: March 30, 2009

By:



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